

REMARKS

The Office Action mailed May 29, 2003 rejected claims 39-59 under 35 U.S.C. 112, first paragraph. The Office Action rejected claims 40-59 under 35 U.S.C. 112, second paragraph. The Office Action rejected claims 39-59 under 35 U.S.C. 102(e) over US 6,258,577 (Goodrich). The Office Action rejected claims 39-59 under 35 U.S.C. 103(a) over US 3,920,650 (Spencer), US 2,825,729 (Petering) and US 6,258,577 (Goodrich). Claims 62 and 63 were said to be allowable.

The Examiner is thanked for a telephone interview with the undersigned on November 6, 2003, in which the rejections were discussed.

The Amendments

Claim 39 has been amended to specify biologically active protein derived from blood. This amendment to claim 39 is supported in the specification on page 27, lines 11-20. Claim 39 has been amended to add the limitation that R1, R4, R5 are not all methyl groups when all of R2, R3 and R6 are hydrogens. This amendment to claim 39 is supported by the specification as filed on page 10, line 16. Claim 39 has been amended to clarify the blood constituent is other than water. This amendment to Claim 39 is supported by the Specification as filed on page 27, lines 8-11. Claims 40-59 have been amended for clarity. No new matter is added by any amendment, and all amendments are supported by the specification as filed.

Restriction/Election

Applicant confirms election of Group II, claims 39-63 with traverse for reasons of record.

Rejection under 35 U.S.C. 112, first paragraph

In the Office Action mailed May 29, 2003, claims 39-59 were rejected under 35 U.S.C. 112, first paragraph. The Office Action stated: "the claims are not commensurate in scope as to the possibilities for the term 'biologically active protein' in claim 39. The term is open-ended and all encompassing. . . There is no definition in the specification for the term except the mentioning that such a protein can be a therapeutic protein (see page 6). . . Without the disclosure of the nature of the biologically active protein, one having ordinary skill in the art would have to undergo undue experimentation to determine which biologically active protein to use to practice the present invention."

The biologically active protein which is a member of the composition of claim 39 is defined in the specification on page 22, lines 16-19, "The term 'biologically active' means capable of effecting a change in a living organism or component thereof. 'Biologically active' with respect to 'biologically active protein' as referred to herein does not refer to proteins which are part of the microorganisms being neutralized." Proteins which are "capable of effecting a change in a living organism or component thereof" are well known in the art and it would not require any undue experimentation to make and/or use the invention. In addition, the specification states "fluids containing biologically active proteins other than those derived from blood may also be treated by the methods of this invention. Such fluids may also contain one or more components selected from the group consisting of protein, e.g. biologically active protein such as therapeutic protein, blood and blood constituents, without destroying the biological activity of such components" on page 23, lines 2-6. The specification continues on page 23, lines 12-14: "So long as fluid components retain sufficient biological activity to be useful for their intended or natural purposes, their biological activities are not considered to be substantially destroyed." A list of therapeutic protein compositions is given in the specification on page 27, lines 11-18.

To advance prosecution, the limitation "derived from blood" has been added to claim 39. This amendment was discussed in the telephone interview with the Examiner on November 6, 2003. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of claims 40-59 under 35 U.S.C. 112, second paragraph

Claims 40-59 were rejected under 35 U.S.C. 112, second paragraph. The Office Action stated "Claims 40-50 are compound claims that are dependent from claim 39 which is a composition claim without a specific reference to a compound. It is unclear what the term 'the compound' refers to."

In response, claims 40-59 have been amended to replace the word "compound" with "composition", and clarify the substituents are present in the photosensitizer. These amendments are believed to overcome the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of claims 39-59 under 35 U.S.C. 102(e)

Claims 39-59 were rejected under 35 U.S.C. 102(e) as anticipated by Goodrich (US 6,258,577). The Office Action stated "The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e))." The application being examined was filed on February 5, 2001 and published as United States Patent Application 20010024781 on September 21, 2001 under 35 U.S.C. 122(b). Therefore, the post-AIPA 35 U.S.C. 102(e) is believed to apply. At this stage, it is not believed a different result would occur if pre-AIPA 35 U.S.C. 102(e) is applied.

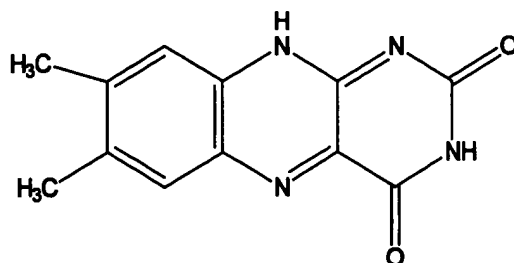
The Office Action stated "Goodrich teaches the use of alloxazines such as 7,8,10-trimethylisoalloxazine to inactivate microorganisms in fluids that contain biologically active protein, blood, and blood constituents by mixing the compounds with the material to be decontaminated (see cols. 3-6)."

In response, the photosensitizers of the present invention are not disclosed in the Goodrich patent. Goodrich discloses photosensitizers "known to the art to be useful for inactivating microorganisms" as useful in the invention in column 4, lines 47-49. The present invention includes photosensitizers "except those previously known to the art" (page 11, lines 19-20).

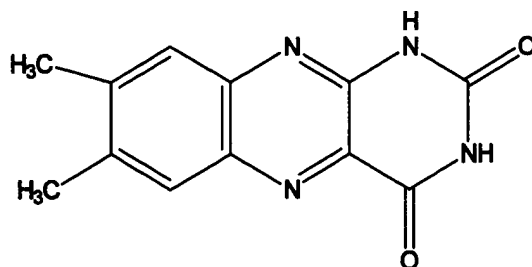
Also, the compounds listed in Goodrich (column 5 and 6) are not included in the present invention. Only the first and third compounds shown in column 5 have the backbone of the photosensitizer shown in claim 39. The first compound shown in column 5 is expressly excluded by the limitation in claim 39 "provided that R1 is neither H nor -OH nor a straight chain alkyl group where the second carbon of the chain is substituted with -OH or =O." The third compound shown in column 5 of the Goodrich patent is excluded by the new limitation in claim 39. This limitation is supported by the specification as filed on page 10, line 16.

In the telephone interview on November 6, 2003, the Examiner indicated the second compound on column 5, lines 30-35 of US 6,258,577 is a resonance structure that encompasses the compound of claim 39. The second compound on column 5, lines 30-35 of US 6,258,577 discloses lumichrome (7,8-dimethylalloxazine). The tautomer is 7,8-dimethylisoalloxazine. The structures in question are shown below.

7,8-dimethylisoalloxazine



Lumichrome (7,8-dimethylalloxazine)



Lumichrome is an alloxazine. It is more stable than its isomeric structure, isoalloxazine. Isoalloxazine is unstable and rapidly converts to lumichrome. The two structures differ by the position of a double bond and a hydrogen atom. Alloxazine has the double bond in the central ring which allows that ring to become aromatic and benefit from aromatic resonance. Aromaticity is not present in the central ring of isoalloxazine. Lumichrome is not encompassed in the present claims.

In addition, the second compound on column 5, lines 30-35 of US 6,258,577 (lumichrome) is not water soluble and therefore does not fall within the claims. See attached pages from Merck Index - Exhibit A showing solubility data of lumichrome.

In view of the above, it is believed the rejection is overcome. Reconsideration and withdrawal of the rejections is respectfully requested.

Rejection of claims 39-59 under 35 U.S.C. 103(a) over Spencer and Petering

Claims 39-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Petering. The Office Action stated: "the term 'blood constituents' reads on water. For this reason, the amended composition claim is not blood-product specific and the composition of the present invention is patently indistinguishable from the composition in the reference, which is composed of water and the isoalloxazine compound."

It is noted that in response to the agreement in the interview dated January 28, 2003, the claims were amended to composition claims comprising (a) a member selected from the group consisting of biologically active protein, blood, and blood constituents; and (b) a water soluble blood product additive photosensitizer. Neither Spencer nor Petering discuss a water soluble photosensitizer, so the composition claimed is neither anticipated nor made obvious by Spencer or Petering.

In addition, the term "blood constituents" is described in the specification on page 27, lines 8-11. "Examples of materials which may be treated by the methods of this invention are whole blood and aqueous compositions containing biologically active proteins derived from blood or blood constituents. Packed red cells, platelets, and plasma (fresh or fresh frozen plasma) are exemplary of such blood constituents." To advance prosecution, Claim 39 has been clarified to indicate blood constituent other than water.

Appl. No. 09/777,727
Amdt. dated November 25, 2003
Reply to Office Action of May 29, 2003

In view of the above, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of claims 39-59 under 35 U.S.C. 103(a) over Goodrich

Claims 39-59 were rejected under 35 U.S.C. 103(a) over Goodrich (US 6,258,577). Both the subject application and the Goodrich patent are commonly owned, therefore, 103(c) applies and the rejection is moot. A Notice of Recordation of Assignment for Serial Number 09/119,666 (US 6,258,577) showing assignment from the inventors to Cobe Laboratories, Inc. and name change of Cobe Laboratories, Inc. to Gambro, Inc. is included. Also included is a Notice of Recordation of Assignment for the present application (Serial No. 09/777,727) showing assignment from the inventors to Gambro, Inc.

In view of the above, reconsideration and withdrawal of the rejection is respectfully requested.

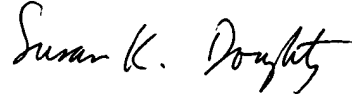
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CONCLUSION

In view of the above arguments and amendments, it is believed claims 39-59, 62 and 63 are allowable. Reconsideration and withdrawal of all rejections is respectfully requested. If there are any issues remaining to passage of the case to issuance, the Examiner is respectfully requested to telephone the undersigned.

This response is accompanied by a Petition for Extension of Time (3 months) and a check in the amount of \$950.00 for the extension of time fee for a large entity. If the amount submitted is incorrect, however, please deduct the appropriate amount, including any extensions of time required, or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



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Attorney docket No. 66-99A
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